

JAN 25 2001

K003460

Attachment 4

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the Clear *Light*TM Nd:YAG Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Palomar Medical Technologies, Inc.

Address: 82 Cambridge St.
Burlington, MA 01803

Contact Person: Marcy Moore

Telephone: 919-363-2432

Preparation Date: 11/01/00

Device Trade Name: Palomar Clear *Light*TM Nd:YAG Laser System

Common Name: Q:Switched Nd:YAG

Classification Name: Laser surgical instrument for use in General and Plastic Surgery and in Dermatology
(see: 21 CFR 878-4810).
Product Code: GEX
Panel: 79

Legally-Marketed Predicate Device: Continuum Biomedical Medlite IV
K970808; K983054

System Description: The complete system consists of a power supply unit, a cooling unit, a foot switch, and the hand piece that connects the laser unit and cooling unit using an umbilical cord. In standard use, the hand piece is held against the treatment area and the light pulse is delivered when the foot switch and hand switch is depressed. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

Intended Use of the Device:

The Palomar Clear *Light*TM Nd:YAG is indicated For removal of tattoos, pigmented and vascular lesions, and hair in Dermatology and Plastic Surgery.

Performance Data:

The differences in the specifications of the laser and the predicate device do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the Palomar Clear *Light*TM Nd:YAG Laser System is substantially equivalent to the legally-marketed claimed predicate device, i.e., the ConBio Medlite IV.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2001

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Inc.
131 Kelekent Lane
Cary, North Carolina 27511

Re: K003460
Trade Name: Palomar Clear Light™ Nd:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: November 2, 2000
Received: November 7, 2000

Dear Ms. Moore:

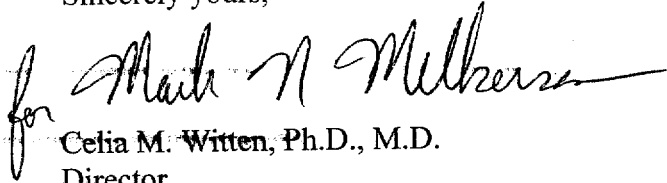
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(K) Number: K 003460

Device Name: Palomar Clear *Light*TM Nd:YAG Laser System

Indications for Use:

The Palomar Clear *Light*TM Nd:YAG laser system is indicated at the 1064 nm wavelength for dark ink tattoo removal, removal of pigmented lesions (particularly Nevus of Ota), and the removal or lightening of hair. The 532 nm wavelength is indicated for the removal of red ink tattoos, treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g., lentigines, ephlides).

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use ☐
(per 21 CFR 801.109)

for Mark N. Milken
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 003460